DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6010

October 2, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gerald R. Tighe
President
Med Prep Consulting, Inc.
1775 Route 34, Unit #9
Farmingdale, New Jersey 07727

02-NWJ-01

Dear Mr. Tighe:

During an inspection of your facility in Wall, NJ, on April 9, 10, 12, & 19, 2001, an investigator from our office documented serious deviations from Title 21, Code of Federal Regulations (21CFR), Parts 210, 211, and 600. These deviations cause your products, [redacted] and [redacted], to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (FD&C Act). These deviations also cause your biological drug products to be in violation of the licensing requirements within the meaning of Section 351 of the Public Health Service Act (PHS Act).

Your firm is not manipulating the licensed biological products [redacted] and [redacted] within the Food and Drug Administration (FDA)-approved labeling. Because you are re-entering single-dose vials and storing the product in syringes (not included in the approved labeling), this is considered to be a new biological drug product which you are manufacturing and distributing without a license. You should immediately cease the process of re-entering single-dose vials and storing the product in syringes until you have submitted and received approval of Biological License Applications (BLA) for these products from the Center for Biologics Evaluation and Research (CBER).

The violations of the regulations that cause these products to be adulterated according to the FD&C Act were presented to you at the close of the inspection on a Form FDA-483, List of Inspectional Observations, and included the following:

1. Your firm manipulated product in direct contradiction to the manufacturers' package inserts, thereby compromising the sterility assurance of the product. Specifically, single-use, preservative-free vials of [redacted] and [redacted] are routinely entered more than once even though the package inserts state "Do not re-enter the vial."

2. Your firm failed to have master batch records for the batching of sterile [redacted] and [redacted] and failed to have a procedure for the preparation of master batch records.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility as a manufacturer to assure that the drug products you produce are in compliance with the requirements of the Act and the regulations promulgated under it. You should take prompt action to correct the deficiencies; failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

We have received your responses dated May 14, June 13, and July 3, 2001; they have all been made part of our official file. We are still reviewing the adequacy of your proposed actions regarding the products handled at your facility, other than [redacted] and [redacted], and cannot comment at this time. However, we find that your responses regarding the manipulations performed on [redacted] and [redacted] are insufficient and incorrect. Your June 13, 2001 response indicates that you are contractually obligated to use multiple-dose vials. While this may be correct, our investigator was informed and observed that your firm was using single-dose, preservative-free vials of [redacted]. [redacted] is only supplied in single-dose, preservative-free vials; therefore, it is impossible for you to use multiple-dose vials. Any stability studies performed by the manufacturer of [redacted] used multiple-dose vials containing preservative and thus those results are not valid for your purposes.

You should notify this office in writing within 15 working days of receipt of this letter of the specific actions you will take in response to this letter and any additional corrective actions you have made since your July 3, 2001 correspondence. Please include a detailed explanation of each step being taken to prevent the recurrence of similar conditions. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed. Your reply should be addressed to: U.S. Food and Drug Administration, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054, Attn: Sarah A. Della Fave, Compliance Officer.

Sincerely,

Douglas I. Ellsworth
District Director
New Jersey District